

**PATENT COOPERATION TREATY**  
**PCT**  
**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**  
(Chapter II of the Patent Cooperation Treaty)  
(PCT Article 36 and Rule 70)


REC'D 24 JAN 2006

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Applicant's or agent's file reference JP802751/142	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/NZ2004/000216	International filing date (day/month/year) 13 September 2004	Priority date (day/month/year) 19 September 2003
International Patent Classification (IPC) or national classification and IPC  Int. Cl. C08L 89/00 (2006.01) C08H 1/06 (2006.01) C08L 89/04 (2006.01) C08H 1/00 (2006.01) C08J 5/18 (2006.01) C08L 89/06 (2006.01)		
Applicant KERATEC LIMITED et al.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
- a. ☒ (sent to the applicant and to the International Bureau) a total of 3 sheets, as follows:
- ☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
- ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
- b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:
- ☒ Box No. I Basis of the report
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

Date of submission of the demand 22 March 2005	Date of completion of this report 11 January 2006
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer  ALBERT S. J. YONG Telephone No. (02) 6283 

## Box No. I Basis of the report

## 1. With regard to the language, this report is based on:

☒ The international application in the language in which it was filed☐ A translation of the international application into \_\_\_\_\_, which is the language of a translation furnished for the purposes of:☐ international search (under Rules 12.3(a) and 23.1 (b))☐ publication of the international application (under Rule 12.4(a))☐ international preliminary examination (Rules 55.2(a) and/or 55.3(a))2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:☐ the international application as originally filed/furnished☒ the description:

pages 1-17 as originally filed/furnished

pages\* received by this Authority on \_\_\_\_\_ with the letter of

pages\* received by this Authority on \_\_\_\_\_ with the letter of

☒ the claims:

pages as originally filed/furnished

pages\* as amended (together with any statement) under Article 19

pages\* 18-20 received by this Authority on 15 August 2005 with the letter of 15 August 2005

pages\* received by this Authority on \_\_\_\_\_ with the letter of

☒ the drawings:

pages 1/3 – 3/3 as originally filed/furnished

pages\* received by this Authority on \_\_\_\_\_ with the letter of

pages\* received by this Authority on \_\_\_\_\_ with the letter of

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.3. ☐ The amendments have resulted in the cancellation of:☐ the description, pages☐ the claims, Nos.☐ the drawings, sheets/figs☐ the sequence listing (*specify*):☐ any table(s) related to the sequence listing (*specify*):4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).☐ the description, pages☐ the claims, Nos.☐ the drawings, sheets/figs☐ the sequence listing (*specify*):☐ any table(s) related to the sequence listing (*specify*):

\* If item 4 applies, some or all of those sheets may be marked "superseded."

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**Box No. V** Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims 2, 26-28	YES
	Claims 1, 3-25	NO
Inventive step (IS)	Claims	YES
	Claims 1-28	NO
Industrial applicability (IA)	Claims 1-28	YES
	Claims	NO

**2. Citations and explanations (Rule 70.7)****CITATIONS**

D1. US 4135942

D2. WO 2003/018673

D3. WO 1992/002238

D4. JP 06220713

D5. JP 05320358

D6. CN 1425813

D7. CN 1403643

In response to the written opinion dated 8 November 2004, the Attorney asserts that the only relevant citation is D2 and that claims 1-22 have been amended such that the polymer is limited to PVA or PVP.

With respect, the Attorney has not put forward any arguments as to why the other six citations have been considered irrelevant. It should be noted that the polymer materials defined in claims 21-28 have not been limited to PVA and PVP. In any case, these are not the only polymers deemed suitable for use in formulating the present composition. On page 4, lines 5-6, it is clearly stated that PEG may be selected as the water soluble polymer and on page 10, lines 27-29, it is stated that acrylates and epoxy acrylates-based monomers are also suitable.

**NOVELTY**Claims 1,3-25

These claims are considered not novel in the light of citations D1-D7. Each of citations D1-D3 discloses compositions comprising keratin and polyethylene glycol. Hence, claims 21-25 are not novel when compared with these citations.

Citations D4-D7 disclose compositions comprising keratin and PVA and therefore claim 1 is not novel when compared with these citations. D5 also discloses the use of cross-linking agents and D6 and D7 disclose the making of keratin fibres. Hence, citations D4-D7 also render claims 3-25 not novel.

**INVENTIVE STEP**

Claims 1,3-25: These claims are considered to lack an inventive step for the same reasons given above.

Claims 2,26-28: The features added by these claims merely amount to common general knowledge and hence they are considered as lacking an inventive step.

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**Box No. VIII** Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

1. Claims 1 and 21 lack clarity in that the expressions "intimate mixture" and "chemically linked" have not been clearly defined in either the description or the claims. It appears from the written submission that the Applicant intends to give a technical meaning to each of these expressions. If that's the case, then it should be made clear.

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received 15 August  
2005**Claims**

1. A material comprising an intimate mixture of keratin protein and a water soluble polymer, the polymer selected from the group comprising:
  - (a) poly (vinyl alcohol) (PVA) and
  - (b) poly (vinyl pyrrolidone) (PVP).
2. A material according to claim 1 wherein the keratin protein is s-sulfonated.
3. A material according to claim 1 or claim 2 wherein the keratin protein is a keratin protein fraction.
4. A material according to claim 3 in which the keratin protein fraction is from the intermediate filament protein family.
5. A material according to any one of claims 1-4 in which the keratin protein is intact.
6. A material according to any preceding claim in which the material is a film, fibre or membrane.
7. A method for making a material comprising
  - (a) mixing a keratin protein and a water soluble polymer to form an intimate mixture, the polymer selected from the group comprising:
    - i. poly (vinyl alcohol) (PVA) and
    - ii. poly (vinyl pyrrolidone) (PVP).
  - (b) casting the aqueous mixture so produced; and
  - (c) drying to create a material.
8. A method for making a material comprising:
  - (a) mixing a keratin protein and a water soluble polymer to form an intimate mixture, the polymer selected from the group comprising
    - i. poly (vinyl alcohol) (PVA) and
    - ii. poly (vinyl pyrrolidone) (PVP)
  - (b) extruding the aqueous mixture produced from step (a) into a coagulation bath through a process of wet spinning.

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9. A method for improving the physico-mechanical properties of the materials produced by any one of claims 7-8 by introducing a cross-linker agent to form disulfide bonds and thus remove sulfonate functionalities.
10. A method according to claim 9 in which the cross-linking agent used as a reductant is a thiol or thioglycollate salt.
11. The method according to claim 9 or claim 10 in which the physico-mechanical properties are wet and dry strength.
12. A method according to claim 10 in which the thioglycollate salt is ammonium thioglycollate solution.
13. The method according to any one of claims 7-12 wherein the keratin protein is s-sulfonated.
14. The method according to any one of claims 7-13 wherein the keratin protein is a protein fraction.
15. The method according to claim 14 wherein the keratin protein is from the intermediate filament protein family.
16. The method according to any one of claims 7-15 in which the keratin protein is intact.
17. A method of improving the wet strength properties of the materials produced by the method of any one of claims 7-8 by incorporating a cross-linking agent into them.
18. A method according to claim 17 in which the cross-linking agent is a protein in to the intimate mixture.
19. A method according to claim 17 in which the cross-linking agent is selected from the group consisting of formaldehyde and glutaraldehyde.
20. A process for improving the mechanical properties of a material produced by a method of any one of claims 7-8 by heat treating the composite matrix to enhance its crystalline properties.

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21. A keratin protein derivative material in which the keratin is chemically linked to a monomer or a polymer material.
22. A keratin protein derivative according to claim 21 in which the keratin protein is s-sulfonated.
23. A keratin protein derivative according to claim 21 in which the keratin is a keratin protein fraction.
24. A keratin protein derivative according to claim 23 in which the keratin protein fraction is from the intermediate filament protein family.
25. A keratin protein derivative according to any one of claims 21-24 in which the keratin is intact.
26. A keratin protein derivative according to any one of claims 21-25 in which the monomer or polymer material is from the acrylate, epoxide or anhydride group.
27. A keratin homopolymer material according to any one of claim 21-26 which is further polymerised.
28. A keratin material according to claim 27 in which has been further polymerised in the presence of an additional monomer from the acrylate, epoxide or anhydride group, to form a keratin copolymer material.

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